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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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*Ex parte*

GLENN J. GORMLEY, KEITH D. KAUFMAN, ELIZABETH STONER,  
and JOANNE WALDSTREICHER

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Appeal 2007-2108  
Application 10/010,678  
Technology Center 1600

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DECIDED: April 22, 2008

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Before TONI R. SCHEINER, DEMETRA J. MILLS, and ERIC GRIMES,  
*Administrative Patent Judges.*

SCHEINER, *Administrative Patent Judge.*

DECISION ON APPEAL

Appellants appeal under 35 U.S.C. § 134 from a final rejection of claims 28-37, all the claims remaining in the application, as obvious over the prior art. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

### STATEMENT OF THE CASE

The claims stand rejected under 35 U.S.C. § 103(a) as unpatentable over Goldman (U.S. Patent 5,407,944, issued April 18, 1995).

Claims 28, 30, and 36 are representative, and read as follows:

28. A method of treating androgenic alopecia consisting essentially of transdermally administering to a person in need of such treatment a therapeutically effective amount of a 5alpha-reductase 2 inhibitor.

30. The method according to claim 28, wherein the 5alpha-reductase 2 inhibitor is transdermally administered by a transdermal skin patch.

36. A transdermal skin patch consisting essentially of a therapeutically effective amount of a 5 alpha-reductase 2 inhibitor as the active ingredient.

### FINDINGS OF FACT<sup>1</sup>

#### *The Present Specification*

1. According to the Specification, “[t]he term ‘treating androgenic alopecia’ is intended to include the arresting and/or reversing of androgenic alopecia, and the promotion of hair growth” (Spec. 5: 22-24).
2. The Specification teaches that “a low daily dosage of a 5α-reductase 2 inhibitor is particularly useful in the treatment of androgenic alopecia” (Spec. 2: 27-28).
3. In addition, the Specification teaches that androgenic alopecia can be treated with “a 5α-reductase 2 inhibitor, e.g. finasteride, . . . in combination with a potassium channel opener, such as minoxidil” (Spec. 5: 23-25).

#### *The Claimed Invention*

<sup>1</sup> Abbreviated “FF”.

4. “Claims 28, 29 and 31-34 specify that the method of treating androgenic alopecia *consists essentially of* transdermally administering . . . a therapeutically effective amount of a 5 $\alpha$ -reductase 2 inhibitor” (App. Br. 6, emphasis added); “[c]laims 30 and 35 . . . add the limitation that the 5  $\alpha$ -reductase [2] inhibitor . . . is administered via transdermal patch” (App. Br. 7); and “[c]laims 36 and 37 are directed to a transdermal skin patch *consisting essentially of* a 5  $\alpha$ -reductase 2 inhibitor . . . as the active ingredient” (App. Br. 8, emphasis added).

*Goldman*

5. Goldman describes “treatment of various types of baldness, in particular, male pattern baldness (MPB) or alopecia” (Goldman, col. 2, ll. 51-52), by administering “a therapeutically effective amount of a mixture of agents, preferably comprising a vasodilator in combination with an estradiol and/or a 5- $\alpha$ -reductase inhibitor” (Goldman, col. 2, ll. 43-46).

6. The agents “need not be administered in the same manner, i.e., one or more may be administered topically while another may be administered systemically” (Goldman, col. 2, ll. 65-68). “Based upon ease of treatment, however, in a highly preferred embodiment the selected agents are administered from a single vehicle in unit dosage form, including tablet, capsule, and transdermal patches or preparation” (Goldman, col. 3, ll. 6-10).

7. “[A] pharmaceutical preparation in unit dosage form . . . to promote hair growth may be prepared comprising, per unit dosage, at least two active agents selected from the group consisting of minoxidil [a vasodilator], estradiol and finasteride” (Goldman, col. 6, ll. 26-30).

8. “Such unit dosage preparations may be adapted for oral administration as a tablet, capsule, liquid, powder, bolus or the like. They may likewise be prepared in unit dosage form in an ingestible or injectable or topical form” (Goldman, col. 6, ll. 34-38).

9. “For topical administration, pharmaceutically-acceptable vehicles in the form of creams, oils, ointments, gels, pastes, liquids, powders, sprays, dips, transdermal patches, and other delivery modes known to those skilled in the art may be utilized” (Goldman, col. 6, ll. 12-16).

#### DISCUSSION

We agree with the Examiner’s conclusion that “[i]t would have been obvious for one skilled in the art to have treated androgenic [alopecia] by transdermal administration of a pharmaceutical preparation, e.g. a transdermal skin patch, consisting essentially of a 5  $\alpha$ -reductase [2] inhibitor, e.g. finasteride” (Ans. 4), given Goldman’s teaching that androgenic alopecia can be treated by administering finasteride, a 5  $\alpha$ -reductase 2 inhibitor, in combination with minoxidil (FF 5, 6), through a transdermal patch (FF 8, 9).

Appellants contend that “the expression ‘consisting essentially of’ does not permit additional active ingredients” (App. Br. 6), or “elements that would have essential significance in the combination” (*id.*), “such as [Goldman’s] vasodilators and estradiol” (*id.*). Appellants contend that Goldman’s “additional active ingredients . . . affect the basic characteristics of the transdermal administration of a 5 $\alpha$ -reductase 2 inhibitor as part of a method for treating androgenic alopecia by providing a SECOND and/or

THIRD active agent for hair growth and are not encompassed by the presently drafted claims” (Reply Br. 5).<sup>2</sup>

Appellants’ arguments are not persuasive. Appellants cite no authority - and we know of none - that supports the proposition that the transitional phrase “consisting essentially of” excludes the administration of additional active ingredients, or the presence of elements of “essential significance in the combination,” per se (App. Br. 6). Rather, it is well settled that

“[c]onsisting essentially of” is a transition phrase commonly used to signal a partially open claim in a patent. Typically, “consisting essentially of” precedes a list of ingredients in a composition claim or a series of steps in a process claim. By using the term “consisting essentially of,” the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention. A “consisting essentially of” claim occupies a middle ground between closed claims that are written in a “consisting of” format and fully open claims that are drafted in a “comprising” format.

*PPG Industries v. Guardian Industries Corp.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998).

In any case, Appellants have not explained how or why Goldman’s additional active ingredients would affect the basic and novel properties of the claimed invention. The basic and novel properties of the claimed invention can be inferred from the Specification’s teaching that “a low daily

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<sup>2</sup> We note the submission of an Evidence Appendix with Appellant’s Reply Brief of May 26, 2006. There is no indication that the Examiner admitted this new evidence, and we have not considered it, or any arguments based on it. 37 C.F.R. §§ 41.33(d)(2) and 41.41(a)(2).

dosage of a 5 $\alpha$ -reductase 2 inhibitor is particularly useful in the treatment of androgenic alopecia” (Spec. 2: 27-28; FF 2), where “[t]he term ‘treating androgenic alopecia’ is intended to include the arresting and/or reversing of androgenic alopecia, and the promotion of hair growth” (Spec. 5: 22-24; FF 1). That is, it can be inferred from the Specification that the basic and novel properties of administering a 5 $\alpha$ -reductase 2 inhibitor include arresting and/or reversing hair loss due to androgenic alopecia, and promoting hair growth.

Appellants have not established that administering a vasodilator and/or estradiol in combination with a 5 $\alpha$ -reductase 2 inhibitor would materially affect these basic and novel properties. Indeed, the Specification teaches that androgenic alopecia can be treated with “a 5 $\alpha$ -reductase 2 inhibitor, e.g. finasteride, . . . in combination with a potassium channel opener [i.e., a vasodilator], such as minoxidil” (Spec. 5: 23-25; FF 3), without qualification. Therefore, we do not agree with Appellants that the term “consisting essentially of” closes the claims to Goldman’s additional ingredients.

In addition, Appellants contend that Goldman “teaches away from the administration of a 5 $\alpha$ -reductase inhibitor via transdermal skin patch” (App. Br. 7), because Goldman’s “other compounds are taught to be present in topical solutions, transdermal systems, creams, or transdermal patches, [but] the 5 $\alpha$ -reductase [2] inhibitor is taught only as a tablet” (*id.*).

This argument is not persuasive. A reference is said to “teach away” from a claimed invention when it “suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the

result sought by the applicant” (*In re Gurley*, 27 F.3d 551, 553, 31 USPQ2d 1130, 1131 (Fed. Cir. 1994)). That is not the case here. Goldman teaches that unit dosage forms containing at least two active ingredients selected from the group consisting of minoxidil, estradiol and finasteride (FF 7) can be prepared in an ingestible or injectable or topical form (FF 8), and that transdermal patches are pharmaceutically-acceptable vehicles for topical administration (FF 9). Appellants have not identified anything in Goldman’s disclosure that suggests that administering a 5 $\alpha$ -reductase 2 inhibitor transdermally is unlikely to be productive.

Appellants’ arguments do not persuade us that the Examiner’s conclusion that the claims are unpatentable over Goldman is in error. Accordingly, the rejection of claims 28-37 under 35 U.S.C. § 103(a) is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv) (2006).

AFFIRMED

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